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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,233	01/04/1999	KEITH HENRY STOCKMAN CAMPBELL	112800.401	2711

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EXAMINER
CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
1632	19

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/225,233	Applicant(s) CAMPBELL ET AL.	
	Examiner Deborah Crouch	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

In the IDS filed October 25, 2001, reference "L", Mclaughlin, is incomplete and therefore has not been considered or made of record. Only the index and pages 40-87 were received. In the IDS filed February 22, 2001, references from DeBeridino, *Genomic Potential of Differentiated Cells* are incomplete as the listing of references cited in these chapters is missing. Once full copies have been filed, the reference will be considered and made of record. There is no need to submit a subsequent 1449.

The term "genetically modified", in claims 23, 37, 48 and 53 is interpreted as containing an exogenous DNA sequence or transgenic (see specification, page 5, line 26 to page 7, line 11).

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 20-22, 24-36, 38-42, 43-47, 49-52, 54 and 55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are not distinguished over a mammalian embryo or mammal found in nature. The claims are to products produced by a particular process. However, neither the mammalian embryo nor the mammal is altered by the process so that the "hand of man" is present. Therefore, the claimed mammalian embryos and mammals are not seen as a new manufacture or composition of matter as required by 35 U.S.C. 101.

Claims 23, 37, 48 and 53 have intentionally been omitted as they encompass transgenic nonhuman mammalian embryos and transgenic nonhuman mammals, which would be altered by the hand of man. (See definition of "genetically modified" above.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20,23,35,37,46,48,51 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 23,37,48 and 53 state that the "cell has been genetically modified prior to nuclear transfer." However, it is not clear if in this instance the resultant mammalian embryo (claim 39 and 48) or mammal (44 and 53) has the same set of chromosomes as a nonhuman, non-embryonic mammal of the same species. The claims encompass a donor cell that is genetically modified after being removed from the donor. In this instance, the resultant embryo and donor would not have the same set of chromosomes as a prior existing mammal. Applicant's claims as written only would encompass the situtation where the donor mammal was transgenic. The claims are being examined as if the cell being transferred is from a transgenic nonhuman mammal as this is the contemplation in the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22,24,29,30,35,36,38,46,47,49-52,54 and55 (sheep) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McLaughlin et al (1990) Reproduction Fertil. Develop. 2, 619-622.

McLaughlin teaches the production of reconstituted sheep embryos and sheep (Merino lambs) by nuclear transfer of the reconstituted sheep embryos, where the donor nucleus is from sheep embryonic cells (page 620, parag. 2-5, and page 621,

parag. 1). Both the sheep embryo and sheep of McLaughlin contains the same set of chromosomes as an individual sheep, that is the same chromosomes as the donor sheep. The source of the donor nucleus, be it sheep embryonic cells as in McLaughlin or a quiescent sheep diploid donor cell as claimed, does not provide a patentable distinction on the resulting sheep embryo or sheep. The source of the donor nucleus does not alter the resultant sheep embryo or sheep such that the sheep embryo or sheep encompassed by applicant's claims are patentably distinct from those of McLaughlin et al. Thus, McLaughlin clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 20-22,25,29,31,35,36,39,46,47,49-52,54 and 55 (pig) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Prather et al (1989) Biology of Reproduction 41, 414-418.

Prather teaches the production of reconstituted pig embryos and pigs by nuclear transfer of the reconstituted pig embryos, where the donor nucleus is from a pig embryonic cell (page 415, col.1, parag. 1 to page 416, line 8, and page 416, col. 2, lines 8-10). Both the pig embryos and pig of Prather contains the same set of chromosomes as an individual pig, that is the same chromosomes as the donor pig. The source of the donor nucleus, be it pig embryonic cells as in Prather or a quiescent pig diploid donor cell as claimed, does not provide a patentable distinction on the resulting pig embryo or pig. The source of the donor nucleus does not alter the resultant pig embryo or pig such that the pig embryo or pig encompassed by

applicant's claims are patentably distinct from those of Prather et al. Thus, Prather clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 20-22,26,29,32,35,36,40,46,47,49-52,54 and 55 (goat) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yong et al (1991) Threiogenology 35, page 299.

Yong teaches the production of reconstituted goat embryos and goats by nuclear transfer of the reconstituted goat embryos, where the donor nucleus is from a goat embryonic cell (parag. 2, and Table). Both the goat embryo and goats of Yong contains the same set of chromosomes as an individual goat, that is the same chromosomes as the donor goat. The source of the donor nucleus, be it goat embryonic cells as in Yong or a quiescent goat diploid donor cell as claimed, does not provide a patentable distinction on the resulting goat embryo or goats. The source of the donor nucleus does not alter the resultant goat embryo or goats such that the goat embryo or goats encompassed by applicant's claims are patentably distinct from those of Yong et al. Thus, Yong clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In*

re Best, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 20-22,27,29,33,35,36,41,46,47,49-52,54 and 55 (mouse) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cheong et al (1993) Biology of Reproduct. 48, 958-963.

Cheong teaches the production of reconstituted mouse embryos and mice by nuclear transfer of the reconstituted mouse embryos, where the donor nucleus is from a mouse embryonic cell (page 959, col. 1, parag. 2 to col. 2, line 10 and page 962, Table 4). Both the mouse embryo and mice of Cheong contains the same set of chromosomes as an individual mouse, that is the same chromosomes as the donor mouse. The source of the donor nucleus, be it mouse embryonic cells as in Cheong or a quiescent mouse diploid donor cell as claimed, does not provide a patentable distinction on the resulting mouse embryo or mice. The source of the donor nucleus does not alter the resultant mouse embryo or mice such that the mouse embryo or mice encompassed by applicant's claims are patentably distinct from those of Cheong et al. Thus, Cheong clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 20-22,28,29,34-36,42,46,47,49-52,54 and 55 (rabbit) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yang et al (1992) Biology of Reproduct. 47, 636-643.

Yang teaches the production of reconstituted rabbit embryos and rabbits by nuclear transfer of the reconstituted rabbit embryos, where the donor nucleus is from a rabbit embryonic cells (page 636, col. 2, parag. 2 to page 639, through parag. 2; page 640, col. 2, parags. 1 and 2, and page 642, Table 4). Both the rabbit embryo and rabbit of Yang contains the same set of chromosomes as an individual rabbit, that is the same chromosomes as the donor rabbit. The source of the donor nucleus, be it rabbit embryonic cells as in Yang or a quiescent rabbit diploid donor cell as claimed, does not provide a patentable distinction on the resulting rabbit embryo or rabbit. The source of the donor nucleus does not alter the resultant rabbit embryo or rabbit such that the rabbit embryo or rabbit encompassed by applicant's claims are patentably distinct from those of Yang et al. Thus, Yang clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 20-22,29,35,36,43-47,49-52,54 and 55 (cows) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147.

Sims teaches the production of reconstituted bovine embryos and bovines by nuclear transfer of the reconstituted bovine embryos, where the donor nucleus is from a bovine cultured inner cell mass cell (page 6145, col. 2, parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). Both the bovine embryo and bovine of Sims contains the same set of chromosomes as an individual bovine, that is the

same chromosomes as the donor bovine. The source of the donor nucleus, be it bovine inner cell mass cell as in Sims or a quiescent bovine diploid donor cell as claimed, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the resultant bovine embryo or bovine such that the bovine embryo or bovine encompassed by applicant's claims are patentably distinct from those of Sims et al. Thus, Sims clearly anticipates the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20,23,35,37,46,48,51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147 in view of Hyttinen et al (1994) Bio/Technology 12, 606-608.

Sims teaches the production of reconstituted bovine embryos and bovines by nuclear transfer of the reconstituted bovine embryos, where the donor nucleus is from a bovine cultured inner cell mass cell or ES cell (page 6145, col. 2, parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). Hyttinen teaches the

production of transgenic bovines, and in particular teaches transgenic bovine multicellular embryos, that is morulae and blastocyst (page 606, col. 2, parag. 2, lines 11-13). The transfer of embryos to recipient female bovines resulted in the birth of a transgenic calf (page 607, col. 2, parag. 1, lines 14-16). Both the bovine embryo and bovine of Sims contains the same set of chromosomes as an individual bovine, that is the same chromosomes as the donor bovine. Thus at the time of the instant invention it would have been obvious to the ordinary artisan to produce a transgenic bovine embryo or a transgenic bovine that contained the same set of chromosomes as an individual bovine by adapting the nuclear transfer methodology of Sims through the use of a transgenic bovine embryo as inner cell mass cell donor given the teachings of Hyttinen of the production of bovine embryos, and especially blastocyst which have an inner cell mass. Sims offers motivation by teaching that the bovine ES cells as nuclear donors in nuclear transfer could allow the production of large numbers of clonal offspring from one valuable embryo or from genetically modified ES cells of one valuable embryo (page 6147, col. 1, lines 2-5). The source of the donor nucleus, an inner cell mass cell, another type of embryonic cell or a quiescent cell, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the resultant bovine embryo or bovine such that the bovine embryo or bovine encompassed by applicant's claims are patentably distinct from those of the combination of art cited above. The cited prior art provides sufficient teaching, suggestion and motivation for the ordinary artisan at the time of the instant invention to reach the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

D.C.
January 24, 2002